

REMARKS

Claims 1, 2 and 9 have been amended to address the rejection for indefiniteness which is considered to be now moot.

New claims 11-13 find support in the description of the working examples at pages 9-15. New claim 14 finds support in the form of a corresponding description at page 12 of applicants' specification.

The rejection of claims 1-10 for obviousness over GB Patent No. 996,089 in view of Barrett-Reis et al is respectfully traversed because: (1) the rejection appears to be based on an erroneous interpretation of GB '089; (2) temperatures within the range of 25-40° C are unsuitable for use in the blood preservation method of GB'089 and (3) the combination of the teachings of Barrett-Reis with the blood preservation method of GB'089 is improper.

Interpretation of GB'089

In the paragraph spanning pages 3 and 4 of the office action the Examiner seems to be combining teachings of GB'089 relating to two very different methodologies with the result being some type of blend that bears little or no resemblance to any methodology taught or suggested by GB'089.

The first methodology disclosed by GB'089 can properly be described as involving blood tests to determine levels of lactic acid in the blood. See page 1, line 78 to page 2, line 32. These tests were conducted to determine why the storage time of erythrocytes at 4° C in actual practice was "less than 30 days" whereas the theoretical storage time of erythrocytes at 4° C projects to 1200 days based on the levels of lactic acid obtained from blood samples incubated at various temperatures as shown in Fig. 1. See page 1, line 83 to page 2, line 9. The invention of GB'089 is based on the discovery that, while the rate of the metabolic reactions that give lactic acid falls with drop in temperature, the "speed of movement of the toxic metabolic products through the cell walls drops considerably faster than the velocity of the metabolic reactions," quoting from page 2, lines 11-15. Note that no clue is given as to the nature of the

assay for lactic acid, other than it can be “directly” applied to measure metabolic products within the red blood cells. See page 2, lines 25-32.

The second method taught by GB’089, while based on the foregoing discovery, does not involve measurement of levels of lactic acid and is not a blood test at all. This second method is a method of blood preservation in which “at least a portion of the intracellular metabolic products of the erythrocytes (e.g. lactic acid) is removed from the erythrocytes during storage and/or intercepted inside the erythrocytes,” quoting from page 2, lines 47-51. One embodiment of the invention involves “feeding appropriate adsorbents in suitable quantity to the blood to be stored,” quoting from page 2, lines 69-71. In another embodiment, apparently referred to by the Examiner, the blood is stored in “containers made of a material which is permeable to low-molecular weight substances, that is, the products of metabolism, such as semipermeable membrane,” quoting from page 2, lines 75-79. In the latter embodiment continuous dialysis is used to remove the metabolic products from the stored blood. GB’089 does not teach or any blood preservation method of the invention would involve any type of test for lactic acid.

Thus, it seems that the examiner has improperly somehow blended a teaching relating to testing that provided the theoretical background of the invention with a description of the invention itself, which is not a blood test.

Test Temperature

At page 4 of the office action the Examiner writes:

“Therefore, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to maintain the erythrocytes in the suspension medium [the preservation method] taught by the GB patent in a temperature range of 25-40° C since Figure 3 of the GB patent [the experimental background] depicts that this temperature range promotes the diffusion of metabolic products such as lactic acid from the interior of the erythrocytes to the exterior, extracellular suspension medium, thus helping to eliminate the deleterious affects caused by these metabolic products.”

Again, the Examiner is improperly combining teachings relating to different concepts. Further, while increasing the temperature would speed diffusion of the metabolic products through a membrane it would also speed up the metabolic reactions. It is respectfully submitted that those skilled in the art would not attempt to store blood at 25-40° C. As shown by the attached, blood is stored either frozen or at a refrigerated temperature of about 4° C. GB'049 contemplates refrigerated storage at 4° C - see page 2, lines 4-6 and the teaching of use of a refrigerator at page two, lines 104-110. One would not use a refrigerator to maintain temperatures above room temperature, e.g. temperatures within the range of 25-40° C.

The Propriety of Combining Barrett-Reis with GB'089

Barrett-Reis et al disclose isolation of red blood cells and plasma, not a storage method. Accordingly, Barrett-Reis cannot properly be characterized as suggesting any modification of a method of blood storage.

New Claims 11-14

No reference of record teaches or suggests any method for measuring glucose concentration (claims 11 and 12), any blood test involving measurement of oxidation-reduction potential in red blood cells and/or plasma (claim 13) or any method involving separate measurements of lactic acid concentrations in the red blood cells and in the plasma and a comparison of those measurements.

In conclusion, the Examiner is respectfully requested to reconsider and withdraw the rejections of record.

Respectfully submitted,

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